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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,831	01/24/2001	David Houze	NOPH/100/JGK	7241

7590 12/30/2003

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/768,831	HOUZE ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 24-36* is/are pending in the application.

4a) Of the above claim(s) *31-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 24-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *21, 23*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The receipt is acknowledged of applicants' request for extension of time, amendment C and IDS, all filed 10/02/2003; and IDS, filed 11/12/2003.

Claims 19-23 have been canceled and claims 31-36 have been added. Claims 1-18 and 24-36 are pending in the application.

1. Newly submitted claims 31-36 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the dermal composition presented by the claims 31-36 comprises two acrylic based polymers, both have functional groups, while the originally presented claims require first acrylic based polymer having substantially no functional groups and second acrylic based polymer having functional groups.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 31-36 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. This application contains claims 31-36 drawn to an invention nonelected. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-18, and 24-30 are included in the prosecution.

3. Claim Rejections - 35 USC § 112

The Standing Rejection:

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The expression "substantially only" is not clearly defining the composition regarding whether or not any other ingredients are present.

Applicant's Arguments:

Applicants argue that the claim language "substantially only" in claim 11 clearly inform the public that in claim 11 the first and the second acrylic based polymers are substantially the only polymers in the dermal composition.

Response to Arguments:

Applicant's arguments above have been fully considered but they are not persuasive. The claim language "substantially only" contradicts with the "comprising"

language of claim 1 that permits the presence of other polymers.

4. Claim Rejections - 35 USC § 102

The Standing Rejection:

Claims 1-4, 6-12, 26, 27, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,994,267 ('267).

US '267 disclosed a dermal composition comprising (1) a drug, (2) a multipolymer that include (I) a mixture of polymers such as ethylene/vinyl acetate with a different polymer such as acrylic acid and (ii) a polyacrylate (abstract; col.2, lines 11-26; col.3, lines 60-65). The polyacrylate constitutes from 5-95% of the multipolymer and contains alkyl acrylate (containing carboxyl functional group), and has functional monomer such as hydroxy ethyl acrylate (col.4, lines 20-35). The acrylate polymer contains from 0-20% of a functional monomers (col.4, lines 20-24). The reference disclosed that the dermal composition permits an unusually low loading of medication as well as high loading of medication into the dermal composition while maintaining the desirable physical properties and release rate (col.2, lines 5-10; col.3, lines 14-16). Examples 8 and 9 show composition comprising mixture of two acrylic polymers: Duro-Tak 80-1194 and Duro-Tak 80-1054. In example 8, the first acrylic polymer forms 2% and the second forms 38% of the total composition and that means the first acrylic polymer forms 5% of the total mixture of the first and second polymers; and example 9 the first polymer forms 32% and the second 2% of the total composition, and this means the first polymer forms 94% of the total mixture of the first and second polymers.

Different polymers will inherently have different solubility and functionality, and one should be higher than the other. The reference disclosed a method for preparing the dermal composition comprising mixing the multipolymers and the drug in an appropriate liquid, casting the mixture and removing the liquid by evaporation (col.3, lines 49-58). The limitations of claims 1-4, 6-11 are met by US '267.

Applicant's Arguments:

US '267 does not teach the composition that includes a polymer composition of two or more polymers which includes a first acrylic based polymer having substantially no functional groups and first solubility parameter, and second acrylic based polymer having functional groups, i.e. functionality.

Response to Arguments:

Applicant's arguments above have been fully considered but they are not persuasive. US '267 disclosed the dermal composition comprising polymers having substantially no functional groups and polymers having functional groups, col.4.

5. Claim Rejections - 35 USC § 103

The Standing Rejection:

Claims 5, 13-18, 24, 25, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,994,267 ('267) in view of US 5,474,783 ('783).

US '267 teaches a dermal composition comprising (1) a drug, (2) a multipolymer that include (I) a mixture of polymers such as ethylene/vinyl acetate with a different polymer such as acrylic acid and (ii) a polyacrylate (abstract; col.2, lines 11-26; col.3, lines 60-65). The polyacrylate constitutes from 5-95% of the multipolymer and contains alkyl acrylate (containing carboxyl functional group), and has functional monomer such as hydroxy ethyl acrylate (col.4, lines 20-35). The acrylate polymer contains from 0-20% of a functional monomers (col.4, lines 20-24). The reference disclosed that the dermal composition permits an unusually low loading of medication as well as high loading of medication into the dermal composition while maintaining the desirable physical properties and release rate (col.2, lines 5-10; col.3, lines 14-16). Examples 8 and 9 show composition comprising mixture of two acrylic polymers: Duro-Tak 80-1194 and Duro-Tak 80-1054. In example 8, the first acrylic polymer forms 2% and the second forms 38% of the total composition and that means the first acrylic polymer forms 5% of the total mixture of the first and second polymers; and example 9 the first polymer forms 32% and the second 2% of the total composition, and this means the first polymer forms 94% of the total mixture of the first and second polymers. Different polymers will inherently have different solubility and functionality, and one should be higher than the other. The reference disclosed a method for preparing the dermal composition comprising mixing the multipolymers and the drug in an appropriate liquid, casting the mixture and removing the liquid by evaporation (col.3, lines 49-58).

US '267 does not teach the amount as claimed in claim 5; the particular drugs

including haloperidol, nicotine, clonidine and scopolamine; and the backing and the release liner.

US '783 teaches a transdermal drug delivery system wherein the a blend of at least two polymers having two different solubility parameters adjusts the solubility of a drug in the polymeric blend and thereby modulate the delivery of the drug from the system and through the dermis. The reference discloses a pressure sensitive adhesive composition which is suitable as a matrix for controlled release of a bioactive agent therefrom comprising a blend of a first polymeric adhesive material having a first solubility parameter and a second polymeric adhesive material having a second solubility parameter, the first and second solubility parameters being different from one another (abstract; col.3, lines 36-60; col.6, lines 13-19). The blend therefore has a characteristic net solubility parameter which can be preselected to adjust the saturation concentration of the bioactive agent in the composition and thereby control its release either upward or downward depending upon whether the rate of release is to be enhanced or retarded (col.4, lines 40-45). The transdermal permeation rate is also controlled by varying the relative proportions of the polymers comprising the multiple polymer adhesive system (col.8, lines 3-5). The blend comprising an acrylic based polymer in an amount of 2-96 % (col.4, lines 15-16; col.9, lines 22-26, 51-54). Drugs used in the composition include haloperidol (col.4, line 1; col.11, line 4), nicotine (col.11, line 8), clonidine (col.10, line 54) and scopolamine (col.11, line 38). Functional monomers used by the reference are acrylic acid, DURO-TAK and hydroxy ethyl

acetate (col.9, lines 21-54; col.15, lines 50-55). The reference teaches a method of preparation of the transdermal delivery device includes the steps of mixing the ingredients, coating the formulation onto protective release liner drying solvents in the oven and applying a backing material and release liner (col.15, lines 20-35; col.4, lines 34, 35).

It is within the skill in the art to select optimal parameters such as ratios and weight percents in order to achieve a beneficial effect, thus the claimed amounts of claim 5 not considered critical, absent evidence of superior and unexpected results.

Thus, it would have been obvious for one having ordinary skill in the art at the time the invention was made to provide a dermal composition comprising a blend of two polymers and select the amount of the first and second polymer according to the desired property (see '267, col.4, lines 59-62), and to provide a transdermal system comprising drug matrix, backing and release liner (as disclosed by US '783), and also select the drug that is known to be delivered transdermally motivated by the teaching of US '783 (in col.3, line 61-col.4, line 2) that antipsychotic (include haloperidol and nicotine), cholinergic agent (include scopolamine), and cardioactive agents (include clonidine) are preferred for delivery in a composition having blend of polymers having different solubility parameters to modulate the delivery of the drugs through the dermis, with reasonable expectation of success to control the rate of drug delivery.

Applicant's Arguments:

Applicants traverse the 103 rejection above by arguing that US '783 does not teach composition comprising two acrylic polymers the first having substantially no functional groups and the second having functional groups. There is no motivation in the references or anywhere to modify the references to arrive to the instant invention that aims at increasing the flux of the drugs across the skin.

Response to Arguments:

Applicant's arguments above have been fully considered but they are not persuasive. The primary reference teaches two acrylic based polymers one having no functional group and second having functional group. The secondary reference US '783 is relied upon for teaching the concept that the dermal composition comprising two polymers having different solubility parameters controls the release of the active agents that claimed by applicants across the skin. Applicants desired to increase the drug flux of certain drugs across the skin, and the secondary reference teaches the achievement of this aspect by mixing two polymers having two different solubility parameters. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art.

See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one having ordinary skill in the art would have been motivated by US '783 that the drugs claimed by applicants including antipsychotic (include haloperidol and nicotine), cholinergic agent (include scopolamine), and cardioactive agents (include clonidine) are preferred for delivery in a composition having blend of polymers having different solubility parameters to modulate the delivery of the drugs through the dermis, with reasonable expectation of success to control the rate of drug delivery.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday-Friday from 7:00 to 5:30 Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali

Patent Examiner

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600